This article has been published in *Medical Law Review* (2021) Published by Oxford University Press, <https://doi.org/10.1093/medlaw/fwab019>

A Normative Framework for the Reconciliation of EU Data Protection Law and Medical Research Ethics

A structured approach to ensure confluence between EU data protection law and medical research ethics

Dara Hallinan

Abstract

EU data protection and medical research ethics overlap in scope and content in numerous instances in which personal data is processed in medical research. It is not always the case, however, that the conditions outlined by the two rule-sets precisely coincide. In the past few years, this lack of confluence has led to confusion as to how the two rule-sets should best relate to one another. This confusion has led to numerous different approaches to the relationship being taken, on occasion leading to counter-intuitive conclusions. Unfortunately, there has hitherto been little effort to provide clarity to this confusion. In this regard, this article attempts to provide a general normative framework aimed at facilitating cogent and just reconciliations of EU data protection law and medical research ethics.

Keywords: bioethics, consent, data protection, GDPR, legitimate processing, research

I. Introduction

EU data protection law and medical research ethics both constitute rule-sets aimed at channelling behaviour in medical research. In many instances when personal data are processed in the course of medical research, these two rule-sets will both outline substantive principles in relation to the same types of action – for example, in relation to the granting and withdrawal of consent. It is not always the case, however, that the two sets of principles will precisely correspond.

In relation to such cases, there has been confusion as to how EU data protection law and medical research ethics should best relate to one another. As a consequence of this confusion, different approaches have been taken with fragmentary and, on occasion, counter-intuitive outcomes. Unfortunately, there have – despite the considerable attention paid to the role of ethics in data protection law generally – been few holistic attempts to bring clarity to this issue.

In this regard, this article attempts to provide a general normative framework which might be used to achieve cogent and just reconciliations of EU data protection law and medical research ethics. The framework is designed at a high level of abstraction to be relevant across all contexts and all discussions in which EU data protection law and medical research ethics overlap. The framework should thus be useful and relevant for academics, policy-makers and practitioners alike.

The article begins with a basic clarification of what is meant by the terms ‘EU data protection law’ and ‘medical research ethics’ as they are used in the piece (section II). The article then turns to make some basic observations as to the relationship between EU data protection law

and medical research ethics. In particular, the article observes that EU data protection law and medical research ethics both form parts of a ‘common normative system of rules’ relating to medical research (sections III and IV).

The article then proposes that such a ‘common normative system of rules’ should always aspire to be both cogent and just. Accordingly, the article subsequently proposes that: whenever EU data protection law and medical research ethics overlap, efforts should be made to reconcile their approaches – to ensure the common normative system of rules remains cogent – and that the substance of such a reconciliation should represent, as far as possible, a ‘normatively ideal’ – just – reconciliation (section V).

In light of this statement, the article observes that, currently, there is a lack of clarity as to how to achieve an optimal reconciliation of EU data protection law and medical research ethics and that this has resulted in sub-optimal suggestions as to how the two rule-sets should relate. The article highlights that the locus of friction is currently the principle of consent – when it should be used and under what conditions. The article also highlights, however, that there is no reason similar issues could not emerge in relation to other instances where EU data protection law and medical research overlap (section VI)

In this regard, the article then moves to outline a normative framework for the reconciliation of EU data protection law and medical research ethics. The first part of this framework, in relation to any given issue, consists of identifying the hard boundaries outlined by data protection law (section VII). The second part of the framework then consists of identifying the ‘normatively ideal’ reconciliation within these boundaries. With regards to this second part, the article suggests that the primary source of normative information should be medical research ethics (section VIII). The article recognises, however, that ethical positions may still, in certain contexts, benefit from the integration of data protection thinking (section IX).

In order to demonstrate the utility of the proposed framework, the article then looks at two cases – two examples – in which EU data protection law and medical research ethics overlap and in which efforts at relating the two rule-sets have led to problematic outcomes – i.e. outcomes which are neither cogent nor reflect a ‘normative ideal’. In each case, the article shows how use of the proposed framework could have resulted in superior outcomes. The first case concerns the interpretation of the concept of ‘freely given’ consent (section X). The second case concerns the hierarchy of justifications for the processing of personal data in medical research (section XI).

Finally, the article briefly considers the courses of action available when no cogent and just reconciliation is possible between EU data protection law and medical research ethics – i.e. where a normatively ideal solution is provided by medical research ethics but is excluded by the hard boundaries of data protection law. In such cases, the article highlights three possible courses of action (section XII). Given that one of these courses of action is the possibility to agitate for legal change, the article finally sketches the possibilities to achieve ongoing legal change in EU data protection law related to medical research (section XIII).

II. Defining ‘EU Data Protection Law’ and ‘Medical Research Ethics’

Prior to engaging in a substantive discussion, a clarification of two key terms used in the article is in order: ‘EU data protection law’ and ‘medical research ethics’. The rationale for this clarification differs by term. In relation to data protection law, clarification is useful to provide readers who may not be familiar with the area of law with insight into the legislation and sources of jurisprudence covered by the term. In relation to medical research ethics,

clarification is useful to demark the specific forms of medical research ethics referred to by the term as it is used in the piece.

By EU data protection law, the article refers, in the first instance, to the range of EU and Member State instruments designed to ensure the fair handling of personal data – i.e. data relating to specific identified individuals – enacted through defined EU legislative procedures and subsequent national legislative procedures enacting legitimate derogations from EU instruments. The most important of these instruments is, without doubt, the General Data Protection Regulation (GDPR) – although other instruments, such as the e-Privacy Directive, also qualify as EU data protection law and are significant in regulating certain types of personal data processing activities.¹ Under the term EU data protection law, the article also includes the range of jurisprudence – at both EU and national level – providing interpretations of the provisions contained in these instruments. By jurisprudence, the article includes both case law and the interpretative guidance of European and national Data Protection Authorities (DPAs).²

By medical research ethics, the article refers to the range of principles and procedures, aimed at elaborating positive obligations with hortatory force in relation to medical research, elaborated by organisations recognised by their respective medical research communities as having the standing to elaborate such principles and procedures – for example professional communities such as the British Medical Association. In other words, the article refers to institutionalised ethical principles and procedures which are, as put recently by Wagner and Delacroix: ‘designed to produce systematic accountability that enables responsible behaviour [in medical research].’³ In this regard, the term medical research ethics excludes all ethical deliberations emerging outside recognised institutional contexts – for example scholarship on the ethics of data processing in medical research.

There is, however, a special case in which principles and processes of medical research ethics, which would otherwise fall within the definition elaborated in the paragraph above, are excluded from the term as it is used in the article: where these principles and processes are explicitly recognised as a relevant source of legal information in EU data protection law itself. For example, Recital 33 of the GDPR recognises that certain forms of non-specific consent may exceptionally be possible in medical research provided – amongst other

¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1; Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) [2002] OJ L 201/37.

² For those unfamiliar with the interpretative structure of EU data protection law, the assertion that interpretations provided by Data Protection Authorities should be considered in terms of jurisprudence may seem strange. This article is not the place to provide an extensive defence of this assertion. However, some brief observations, for the sake of clarity, are in order. First, under EU data protection law, DPAs are explicitly given wide-ranging interpretative powers – see section XIII for further discussion. Second – perhaps owing to the vagueness of the provisions in EU data protection law, the range of plausible interpretations which may be given to these provisions across contexts, and the lack of case law dealing with their interpretation, DPA interpretations have grown to be, *de facto*, treated by practitioners and scholars as jurisprudence. Consider, for example, the reliance on DPA guidance in providing commentary on the law in the following: A Buchholz, R Stentzel, ‘Kapitel II Grundsätze: Artikel 5’ in S Gierschmann, K Schlender, R Stentzel, W Veil. (eds.), *Kommentar Datenschutz-Grundverordnung* (Bundesanzeiger Verlag: Berlin 2017) 173, 173-194; P Reimer, ‘Artikel 5: Grundsätze für die Verarbeitung personenbezogener Daten’ in G Sydow (ed.), *Europäische Datenschutzgrundverordnung: Handkommentar*, (Nomos: Baden Baden 2018) 396, 396-412.

³ B Wagner, S Delacroix, ‘Constructing a mutually supportive interface between ethics and regulation’ (Forthcoming 2020) *Computer Law & Security Review*.

conditions – that these are: ‘in keeping with recognised ethical standards for scientific research’. Such principles and processes are excluded for two reasons. First, and most importantly, in these cases, the law delegates legal power to institutionalised ethics. Accordingly, in such cases, the relevant principles and practices can no longer be regarded as purely ‘ethical’ and as clearly separate from the law. Second, in such cases, the relationship between EU data protection law and medical research ethics is already clarified in the law itself, mooted the need for further consideration.

With the clarification of these two key terms in this section, the stage is set for an entry into the substantive discussion. This discussion begins by elaborating certain key commonalities in the way EU data protection law and medical research ethics engage with the phenomenon of medical research.

III. EU Data Protection Law and Medical Research Ethics: A ‘common system of rules’ for medical research

In the first instance, both EU data protection law and medical research ethics have the same intent to act on the practices involved in medical research. In other words, both rule-sets seek to channel behaviour in medical research.

In this regard, EU data protection law and medical research ethics both share the common purpose of elaborating principles and procedures aimed at resolving conflicts of interest in, and to coordinate behaviour in relation to, medical research. In this regard, they can both be considered as parts of a ‘common system of rules’ dealing with medical research. EU data protection law outlines a range of principles and conditions generally relevant for the processing of personal data which also apply to any processing of personal data for the purposes of medical research. Medical research ethics has, as its core goal, the elaboration of conditions for the conduct of medical research. The World Medical Association’ Declaration of Helsinki, for example, begins with the assertion that: ‘The World Medical Association (WMA) has developed the Declaration...as...principles for medical research involving human subjects.’⁴

The above is not to suggest that the two rule-sets must always engage with the same medical research phenomena. In the first instance, EU data protection law will not always share the same material scope as instruments of medical research ethics. For example, EU data protection law will not apply to any medical research activity not involving the processing of personal data – for example EU data protection law will not apply to clinical trials activity not involving personal data.⁵ In turn, even when EU data protection law and the instruments and processes of medical research ethics do overlap in terms of material scope, they may still diverge in the kinds of substantive issues they address. For example, EU data protection law is largely uninterested in what happens following the return of novel personal data to research subjects in genomic research.⁶ Certain instruments of medical research ethics, however – for example the UNESCO International Declaration on the Human Genome – propose genetic

⁴ World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, (Policy, 1964 (updated 2013)) Para 1.

⁵ See, for example: European Data Protection Board, *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b))* (Policy, 2019) 4 (hereafter European Data Protection Board, *Opinion 3/2019*).

⁶ D Hallinan, *Feeding Biobanks with Genetic Data: What role can the General Data Protection Regulation play in the protection of genetic privacy in research biobanking in the European Union?* (VUB Doctoral Thesis: Brussels, 2018) 363.

counselling be provided to help subjects deal with the unexpected, even unpleasant, surprises resulting from such returns.⁷

The two rule-sets, however, do display substantial overlap in a broad range of cases. In terms of material scope, whenever personal data is processed in medical research, both EU data protection law as well as any relevant principles and processes of medical research ethics will apply. In terms of substantive content, EU data protection law includes a dizzying range of principles and procedures concerning the processing of personal data relevant to medical research. Many of these deal with aspects of medical research with extensive track records of consideration in medical research ethics. Consider, for example, the confluence between the ‘integrity and confidentiality’ principle in Article 5 of the GDPR and the comparable confidentiality principle in paragraphs 9 and 10 of the World Medical Association’s Declaration of Taipei.⁸

It is not simply the case, however, that EU data protection law and medical research ethics both seek to channel behaviour in the medical research context. The two sets of rules also share comparable base rationalia for why they seek to channel behaviour.

IV. EU Protection Law and Medical Research Ethics: A ‘common normative system of rules’ for medical research

In this regard, both EU data protection law and medical research ethics seek to achieve a fair balance between the interests of the research subject on the one hand, and the interests engaged by the conduct and outcome of medical research on the other. In other words, both rule-sets have normative intent.

The normative intent of EU data protection law is expressly declared in Articles 1(1) and 1(2) of the GDPR, which state, respectively: ‘This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data’; and ‘[t]his Regulation protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.’ Highlighting that a law has normative intent may seem obvious. In the case of EU data protection law and medical research, however, recalling the law’s normative intent seems pertinent. Following the entry into force of the GDPR, there has been much effort devoted to the elaboration of the technical applicability of data protection law to medical research. This effort, however, has often resulted in analyses which highlight the law’s technical requirements, without devoting equal weight to discussing the law’s underlying normative intent.⁹

The normative intent of medical research ethics scarcely needs reiteration. All principles and processes of medical research ethics – as the name medical research *ethics* clearly suggests – seek to achieve just outcomes in terms of elaborating a fair balance of interests in medical research. Indeed, this intent is usually made explicit. For example, as the Council for International Organizations of Medical Sciences and World Health Organization state in their International Ethical Guidelines for Health-related Research Involving Humans: ‘The aim of the guidelines was (and still is) to provide internationally vetted ethical principles and

⁷ United Nations Educational, Scientific and Cultural Organization, *International Declaration on Human Genetic Data*, (Declaration, 2003) Art 11.

⁸ World Medical Association, *Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks* (Policy, 2002 (updated 2016)) Paras 9 and 10.

⁹ This observation should not be regarded as a criticism of such analyses. Naturally, it is imperative that the technical applicability of legislation receive attention.

detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings.’¹⁰

It is true that the underlying normative frameworks from which the two rule-sets draw their normative intent are not identical. On the one hand, EU data protection law takes EU fundamental rights as its underlying normative framework. On the other hand, the principles and processes of medical research ethics tend to be built on the back of other normative frameworks. For example, the World Medical Association’s Declarations of Helsinki and Taipei are built around the normative framework provided by bioethics.¹¹ Nor is it the case that the substantive content of these underlying frameworks will always be identical. EU fundamental rights, for example, unlike bioethics, holds no place for a principle of beneficence.¹² In relation to medical research however, these underlying normative frameworks largely converge – and at least seldom contradict – in their vision of the relevant interests at stake and how these should be balanced.¹³

Accordingly, EU data protection law and the principles of medical research ethics might not merely be regarded as forming a ‘common system of rules’ in relation to medical research, but rather as forming a ‘common normative system of rules’ in relation to medical research. Building on this assertion, a set of subsequent propositions might be made as to the general qualities any ‘common normative system of rules’ should have.

V. A ‘Common Normative System of Rules’ should be Cogent and Just

There are numerous assertions that can be made about the substantive qualities a ‘common normative system of rules’ should have. In line with Habermas, however, I would suggest that two substantive qualities stand out as particularly important.¹⁴

First, a ‘common normative system of rules’ should be substantively cogent – in particular, the system should avoid internal inconsistencies and contradictions. At best, such inconsistencies and contradictions will have the consequence that: i) impacted stakeholders will need to invest unnecessary resources in their efforts to distil, and comply with, relevant rights and obligations; and/or ii) that the aims of conditions of the system may not be optimally achieved. At worst, such inconsistencies and contradictions will have the consequence that: i) impacted stakeholders are placed in the awkward, or even impossible,

¹⁰ Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), *International Ethical Guidelines for Health-related Research Involving Humans* (Guidelines 2016) viii.

¹¹ See, for example, the discussion in: P Riis, ‘Thirty years of bioethics: the Helsinki Declaration 1964-2003’ (2003) 1(1) *New Review of Bioethics* 15, 15.

¹² See, for example, the discussion of the difference between medical ethics and human rights generally in: M Peel, ‘Human rights and medical ethics’ (2005) 98 *Journal of the Royal Society of Medicine* 171, 172-173.

¹³ Consider, in this regard, UNESCO’s observations as to the possibility to produce a Declaration of bioethical principles grounded in human rights: ‘the draft declaration...anchors the principles that it espouses firmly in the rules governing human dignity, human rights and fundamental freedoms. Bioethics has hitherto developed substantially along two broad streams. One of these, present since the ancient times, derives from reflections on medical practice and on the conduct of medical professionals. The other, conceptualized in more recent times, has drawn upon the developing international human rights law. One of the important achievements of the declaration is that it seeks to unite these two streams. It clearly aims to establish the conformity of bioethics with international human rights law.’ UNESCO, *Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms in Bioethics* (Explanatory Memorandum, 2005) 12.

¹⁴ J Habermas, *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (William Rehg tr, Polity: Cambridge, 1997) 227-228. I have used Habermas’ straightforward formulation here as I believe it allows the currently pertinent issues to be grasped, structured and addressed. It would, however, be fascinating to conduct similar analyses with other descriptions and conceptualisations of the ideal qualities a ‘common normative system of rules’ should have.

position of necessarily violating one aspect of system in seeking to comply with another aspect of the system; and/or ii) that certain aims or conditions outlined in the system become substantially meaningless or impossible to fulfil.

Second, a ‘common normative system of rules’ should be substantively just. For a system of rules to be regarded as substantively just, it should: i) take into account all relevant stakeholders affected by a given activity; and ii) seek to achieve a fair balance between the competing interests of these stakeholders engaged by the activity. Whether a fair balance has been struck by a given system of rules can only be judged against an underlying normative framework which is contextually relevant in relation to the activity in question and the society in question – in relation to medical research in the EU, for example, the bioethics frameworks or the EU fundamental rights frameworks may be looked to as providing relevant background frameworks. Accordingly, different conclusions as to the fairness of a resolution of interest conflicts is, in theory, possible in relation to a single system of rules.

It should be noted that an optimisation of cogency within a system of rules may not always lead to a concurrent optimisation of justice, and vice versa.¹⁵ This is especially the case when a system of rules consists of a mix of different types of rule-sets. For example, in relation to the focus of this article, optimising the cogency of the ‘common normative system of rules’ may, in certain circumstances – as will be elaborated in more detail in the next sections – mean that principles elaborated in EU data protection law may override principles elaborated in the relevant instruments and processes of medical research ethics. Such an optimisation of cogency through law, however, may sometimes need to happen regardless of whether the aims and conditions elaborated in the relevant instruments and procedures of medical research ethics are substantially more just.

Given that any ‘common normative system of rules’ should be cogent and substantively just, the following observation might be made in relation to the subject of this article: whenever EU data protection law and medical research ethics overlap in terms of the issues they address, efforts should be made that their approaches are reconciled – such that the system remains cogent – and that the content of any reconciliation represents, as far as possible, a ‘normative ideal’ – such that the system remains as just as possible. When, in relation to any given instance, the principles outlined in EU data protection law and medical research ethics are identical, a cogent and just reconciliation – assuming, *prima facie*, that the position taken in both rule-sets is indeed just – is already present. When the principles in the two rule-sets do not obviously converge, however, the question emerges as to how to proceed. Unfortunately, there seems, currently, to be some confusion in this regard.

VI. The Current Lack of Approaches Ensuring Cogent and Just Reconciliation

This confusion has led to different approaches as to how to EU data protection law and medical research ethics should relate. In certain cases, these approaches have led to sub-optimal outcomes in terms of producing a cogent and just set of rules concerning the

¹⁵ As Floridi observes in this regard: ‘When policy-makers, both in political and in business contexts, wonder why we should engage in ethical evaluations when legal compliance is already available...the answer should be clear: compliance is necessary but insufficient to steer society in the right direction. Because digital regulation indicates what the legal and illegal moves in the game are, so to speak, but it says nothing about what the good and best moves could be, among those that are legal, to win the game, that is, to have a better society. This is the task of both digital ethics, on the side of moral values and preferences, and of good digital governance, on the side of management’. L Floridi, ‘Soft ethics, the governance of the digital and the General Data Protection Regulation’ (2016) 376 *Philosophical Transactions A* 1, 4
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6191665/pdf/rsta20180081.pdf> accessed 30 November 2020.

processing of personal data processing in medical research. Unfortunately, there has hitherto been little directed effort to address this confusion.

One example of such an approach is that taken by the European Data Protection Board (EDPB) in choosing to adopt an interpretation of the concept of ‘freely given’ consent in EU data protection law in relation to clinical trials which is at odds with the concept of ‘freely given’ consent in medical research ethics – an example which will be returned to, in detail, in section X.¹⁶ Another example is the position, seemingly dominant in current scholarship, that asserts EU data protection law does not foresee any hierarchy in terms of the justification it provides to legitimate the processing of personal data in medical research, whilst medical research ethics tends to require that, whenever possible, consent is obtained to legitimate processing – an example which will be returned to, in detail, in section XI.¹⁷

The problems in the relationship between EU data protection law and medical research ethics appear, currently, to be concentrated around the issue of consent – when consent should be relied on as a justification for the processing of personal data in research as well as the conditions under which consent should be regarded as legitimate. The reason consent is the locus of problems is likely that: i) consent appears in a highly significant role in both EU data protection and medical research ethics; ii) the specifics of the elaboration of consent in each rule-set leaves room for interpretation, in which divergences in approaches can manifest; and iii) the various possible interpretations are highly consequent for the practice of medical research, driving significant discussion of the topic – for example, the scope of consent in genomic research can be decisive for the forms of research which can eventually be conducted with a given genomic data set.¹⁸

This is not to say, however, that there is any foundational quality to the principle of consent which makes it the only principle in relation to which issues could emerge. There are numerous other principles and issues around which problems could manifest in the relationship between EU data protection law and medical research ethics. For example, there are principles in medical research ethics which work to limit the degree to which sharing of a research subject’s genetic information with family members is possible – in particular principles related to confidentiality.¹⁹ There are certain principles of EU data protection law – for example the right, elaborated in Article 15 of the GDPR, that data subjects have the right to access personal data concerning them – which could be interpreted broadly to, in certain situations involving the processing of genetic information, require that this information be shared with family members.²⁰

¹⁶ European Data Protection Board, ‘*Opinion 3/2019*’ (n 5).

¹⁷ See, for example: Victoria Chico, ‘The impact of the General Data Protection Regulation on health research’ (2018) 128 *British Medical Bulletin* 109, 112 (hereafter Chico, ‘The impact of the General Data Protection Regulation’).

¹⁸ See, for example: Mark Sheehan, ‘Can Broad Consent be Informed Consent?’ (2011) 4(3) *Public Health Ethics* 226, 226.

¹⁹ See, for example: General Medical Council, *Confidentiality: good practice in handling patient information* (Policy 2017) 36-37.

²⁰ The Article 29 Working Party – the forerunner to the EDPB – has, in the past, made certain suggestions in this direction: ‘family members might also be considered as ‘data subjects’’. Article 29 Working Party, *Working Document on Genetic Data* (Policy, 12178/03/EN WP 91, 2004) 8.

The possibility of recognising family members as data subjects under data protection law also has certain scholarly support. Taylor observes: ‘the [concept of] personal data may...be compatible with genetic data being the personal data of secondary data subjects [genetic relatives]’. M Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection* (Cambridge University Press: Cambridge, 2012) 107.

In order to ameliorate this confusion, and the consequences of this confusion, elaboration of a structured ‘normative framework’ within which EU data protection law and medical research ethics can be reconciled in a cogent and just manner seems warranted. This framework might be broken down into two parts. First, in relation to any given issue, there should be an establishment of hard boundaries – i.e. the substantive conditions in relation to which there is no room for any, or any further, flexibility – within which any discussion of reconciliation must take place, and which the substance of reconciliation must respect.

VII. Identifying Hard Boundaries within which Normative Reconciliation Must Take Place via EU Data Protection Law

These hard boundaries can be elaborated by considering the relevant fixed conditions outlined in EU data protection law. One might ask why data protection law should be looked to – rather than medical research ethics – for this initial establishment of boundary criteria. The answer is straightforward, but worth elaborating, nevertheless.

Statutory law is a unique social construct. This form of rules is enacted via the democratic legislative procedure aimed at elaborating conditions for behaviour which are binding and enforceable in relation to society as a whole. The basic aim of such rules – at least in the EU – is to: i) provide programmatic solutions for the resolution of social conflicts; ii) which will be respected by all currently impacted parties, as well as any future parties which engage in regulated activities; and iii) which will provide a stable framework – in relation to the material, temporal and social aspects of regulated activities – within which impacted parties can plan future behaviour and the consequences of behaviour. Only via such a form of rules can complex societies maximize the set of values and goals they find important whilst simultaneously limiting disappointments and negative outcomes.²¹

In this function, statutory law is imbued with a unique social value over and above the value inherent in its concrete provisions. This value is commonly recognised under the term ‘the rule of law’.²² One consequence of this value is that statutory law cannot be overridden by competing rule-sets emerging from alternative legislative procedures. If such an override of statutory law via alternative legislative procedures was possible, then, in relation to any given regulated activity, statutory law could not provide a framework which: i) would need to be respected by current, or future, impacted parties in relation to a regulated activity or; ii) which would provide a stable framework within which impacted parties could plan their behaviour and the consequences of their behaviour. Eventually, statutory law would be unhelpful for society in realising desirable values and goals or minimising disappointments and negative outcomes.

EU data protection law is statutory law. The GDPR, for example, was the result of an extensive and prolonged legislative process at EU level.²³ Medical research ethics, however, is not statutory law. Rather, medical research ethics comprises rules enacted via alternative

²¹ The idea of law as a mechanism for the resolution of conflict and the generalisation of expectations is common in thinking on the sociology of law. See, for example, the discussion of the function of law in society in: N Luhmann, *A Sociological Theory of Law* (Elizabeth King-Utz and Martin Albrow trs, Martin Albrow ed., Routledge: Abingdon, 1st English Paperback Edition, 2014) 22-103.

²² See, for an instructive discussion of the extent of the concept in the EU legal order: T von Danwitz, ‘The Rule of Law in the Recent Jurisprudence of the ECJ’ (2014) 37(5) *Fordham International Law Journal* 1311, 1312-1335.

²³ The first major step in the process had already been taken in 2010 – despite final adoption in 2016 – with the European Commission’s Communication: *A comprehensive approach on personal data protection in the European Union*. European Commission, *A comprehensive approach on personal data protection in the European Union* (Policy, COM(2010) 609 final, 2010).

legislative processes – tendentially centred around the deliberations and decisions of technical expert groups. The outcome of these processes is usually principles and/or processes intended to have hortatory force concerning the specific social phenomenon of medical research.²⁴ Accordingly, the conditions and principles of medical research ethics cannot – and should not – override the conditions of EU data protection law. In this regard, it stands to reason that the conditions of EU data protection law must be looked to as providing the hard boundary criteria within which any reconciliation must take place.

This section clarified that the first part of the framework consists of the clarification, in relation to any given instance of overlap, of the hard boundary criteria within which any discussion of reconciliation must take place, via EU data protection law. The second part of the framework then consists of the identification of a ‘normatively ideal’ reconciliation within these boundaries.

VIII. Identifying ‘Normatively Ideal’ Reconciliations via Medical Research Ethics

In terms of identifying the shape of a ‘normatively ideal’ reconciliation – unlike the establishment of hard boundary criteria – in any given case, the relevant principles and processes of medical research ethics should be looked to as the primary source of information. One might ask why medical research ethics – rather than EU data protection law – should be looked to as the primary source of such information. The answer lies in the difference in the proximity of EU data protection law and medical research ethics to the phenomenon of medical research.

EU data protection law under the GDPR provides limited normative substance concerning medical research. This is true for two reasons. First, the GDPR was drafted at a high level of abstraction, to consist of general principles with common applicability across all sectors in which personal data is processed – from banking, to online behavioural advertising, to medical research etc. Accordingly, the law contains very few specific provisions which aim to outline a normatively ideal balance between the relevant competing interests in the medical research context.²⁵ Second, EU data protection law was drafted to provide procedures which must be followed to permit the legitimate processing of personal data. In this regard, the law includes few provisions which clearly delineate legitimate and illegitimate forms of personal data processing in medical research – i.e. EU data protection law suggests the conduct of research to be in order provided certain procedures for data processing are followed, as opposed to demarking research in terms of substantive legitimacy and illegitimacy.²⁶

In contrast, the principles and processes of medical research ethics have been designed to provide clear normative substance relevant for medical research. This rule-set thus has the capacity to fill both forms of normative gaps left by data protection law. Where data protection law deals in the abstract, medical research ethics deals in the specifics of the medical research context – indeed principles and processes of medical research ethics are

²⁴ See, for example, the discussion in: E Dove, ‘Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework’ (2015) 43(4) *Journal of Law, Medicine and Ethics* 675, 675-689.

²⁵ As Latanzzi observed in relation to prior manifestations of EU data protection law and genomic research, albeit with continued relevance to the situation under the GDPR: ‘it may be helpful to recall that [EU data protection law consists of] omnibus regulation [and does] not provide detailed guidance’. R Lattanzi, ‘Data Protection Principles and Research in the Biobanks Age’ in: D. Mascalcioni (ed), *Ethics, Law and Governance of Biobanking* (Springer: Dordrecht, 2015) 79, 85.

²⁶ The procedural quality of data protection law has been elaborated at length by several scholars. Consider, for example, the discussion in: C Quelle, ‘The ‘Risk Revolution’ in EU Data Protection Law: We Can't Have Our Cake and Eat It, Too’ in R Leenes, R van Brakel, S Gutwirth and P De Hert (eds), *Data Protection and Privacy: The Age of Intelligent Machines* (Hart: Oxford, 2017) 33, 47.

often highly specific in relation to distinctive forms of medical research. Where data protection law lacks concrete substantive prohibitions, medical research ethics endeavours to elaborate such prohibitions wherever necessary. Consider, for example, the extensive range of context-specific substantive principles outlined in the Council for International Organizations of Medical Sciences' International Ethical Guidelines for Health-related Research Involving Humans.

Accordingly, it makes sense that the primary source of information relevant for the identification of 'normatively ideal' reconciliations should be medical research ethics. In this regard, the idea that ethics should be looked to as a source of information to fill normative gaps in law is nothing novel. The recent UK case of *ABC v St George's Healthcare NHS Trust & Others*, for example, highlights this approach in relation to informational harms in the clinical setting. In the case – concerning the disclosure of information about a serious genetic predisposition, without consent, to a family member – the UK High Court specifically observed – referring also to the previous case of *Montgomery v Lanarkshire Health Board* – the utility of imposing new: 'legal obligations...[which are] consistent with...professional guidance.'²⁷

The above sections proposed that, in identifying 'normatively ideal' reconciliations, the primary source of information should be medical research ethics. There are, however, exceptions to this principle in relation to which data protection thinking may augment, or even outweigh, information derived medical research ethics.

IX. Identifying 'Normatively Ideal' Reconciliations via Data Protection Law

Medical research ethics generally consists of normative principles outlined in instruments produced, and processes populated, by specific groups of technical experts. Accordingly, there is no guarantee the specifics of these principles and processes will always be normatively perfect.

This is particularly true as, whilst technical expert groups may have enviable command of certain forms of knowledge as to the normative implications of medical research, there is no guarantee – even with the best intentions and efforts at consultation – that such groups will have command of all relevant knowledge concerning the normative implications of medical research. It is possible that technical expert groups may fail to appreciate relevant developments in the material or social constellations relevant to the normative dimensions of medical research. It is also possible that such groups fail to appreciate developments in the broader legal or ethical contexts relevant to medical research. In such cases, technical expert groups may fail to recognise, or fail to give fair consideration to, all interests engaged by a given form of medical research.²⁸

In certain instances, the logic and thinking around EU data protection law may thus function as a source of normative information which can augment, or even provide superior alternatives, to that provided by the principles and processes of medical research ethics. I would suggest that such situations are likely to emerge in two cases in particular: i) when personal data processing in medical research involves novel constellations of actors – in particular private actors – or novel forms of production, exchange and further processing of

²⁷ *ABC v St George's Healthcare NHS Trust & Others* [2020] EWHC 455 (QB) para 186; *Montgomery v. Lanarkshire Health Board*, [2015] UKSC 11 para 93.

²⁸ See, for a discussion of the limitations on the ability of technical expert groups to achieve perfect solutions in relation to socially significant questions of information processing: J. Cohen, *Between Truth and Power: The Legal Construction of Informational Capitalism* (Oxford University Press: New York, 2019) 232-234 and more broadly 217-237.

personal data, which have not, hitherto, been the subject of extensive consideration in medical research ethics, but which have been the subject of consideration in EU data protection law; and ii) when personal data processing in medical research involves activities engaging emergent social or legal norms which have not, hitherto, been the subject of consideration in medical research ethics.²⁹

For example, there is increasing involvement of information processing corporations in publicly funded medical research. Such corporations may have specific interests – beyond the conduct of research – engaged by the processing of personal data. Such corporations may also have specific modalities of processing which extend beyond those usually associated with medical research. There remains limited consideration in medical research ethics as to which principles should govern the involvement of such corporations in medical research.³⁰ EU data protection law, however, disposes over a broad jurisprudence and scholarship on the activity of such corporations in relation to the processing of personal data – for example concerning consent, and cross-border transfers etc.³¹ This thinking and jurisprudence likely holds valuable normative information capable of – at least – augmenting nascent considerations in medical research ethics.

The previous sections remained theoretical and abstract in their presentation of a general normative framework for the reconciliation of EU data protection law and medical research ethics. Two examples of the application of the framework to current issues concerning the relationship between EU data protection law and medical research ethics should make the discussion more concrete and accessible.

X. Example One: The case of ‘freely given’ consent in clinical trials

The first example concerns the position of the EDPB on the difficulties in gaining ‘freely given’ consent under EU data protection law in clinical trials, outlined in their Opinion on the interplay between the Clinical Trials Regulation and the GDPR.³²

In this position, the EDPB state: ‘a clear situation of imbalance of powers between the participant and the sponsor/investigator will imply that the consent is not “freely given” in the meaning of the GDPR. As a matter of example, the EDPB considers that this will be the case when a participant is not in good health conditions, when participants belong to an economically or socially disadvantaged group or in any situation of institutional or hierarchical dependency’.³³ In this position, the Board takes two significant logical steps in reaching their conclusion. First, the Board decouples the concept of ‘freely given’ consent in

²⁹ For example, data portability is now a legal norm in relation to the processing of personal data in the EU – elaborated in Article 20 of the GDPR. The concept has, however, received little discussion in relation to medical research ethics. There are situations, however, in which questions of the ability to transfer personal data to other parties take on ethical relevance in medical research – in relation to rare diseases and limited data/bodily samples, for example. In such cases, the thinking on data portability in data protection law may provide a useful knowledge base for the elaboration of relevant principles in medical research ethics. See, for example, the extended consideration of the question of the right to data portability in EU data protection law in: Article 29 Working Party, *Guidelines on the right to data portability* (Guidelines, 2016 (revised 2017)).

³⁰ See, for example, the discussion in: A Ballantyne, C Stewart, ‘Big Data and Public-Private Partnerships in Healthcare and Research: The Application of an Ethics Framework for Big Data in Health and Research’ (2019) 11(3) *Asian Bioethics Review* 315, 317-325.

³¹ Consider, for example, the recent CJEU case law on both consent and cross border transfers and information processing corporations: *Orange România SA v Autoritatea Națională de Supraveghere a Prelucrării Datelor cu Caracter Personal (ANSPDCP)* (2020) ECLI:EU:C:2020:901; *Data Protection Commissioner v. Facebook Ireland Ltd, Maximillian Schrems* (2020) ECLI:EU:C:2020:559.

³² European Data Protection Board, ‘*Opinion 3/2019*’ (n 5).

³³ European Data Protection Board, ‘*Opinion 3/2019*’ (n 5) 6.

EU data protection law from all other legal and ethical conceptualisations of the same concept – ‘freely given’ consent – applicable in the same context – clinical trials. Second, the Board then analyses the concept of ‘freely given’ consent from a purely EU data protection perspective in reaching their conclusion.

As a consequence of the EDPB’s approach, their eventual position can be criticised – and indeed has been, for example by Peloquin et. al. – in terms of cogency and in terms of achieving a ‘normative ideal’. In terms of cogency, the position adopted by the EDPB clearly diverges from the general position in medical research ethics on when an individual has the capacity to provide a ‘freely given’ decision – as well as, incidentally, diverging from the position taken in EU clinical trials legislation.³⁴ In terms of a ‘normative ideal’ the EDPB’s position appears to be built solely on reference to prior guidelines on EU data protection law – adopted by the EDPB’s forerunner, the Article 29 Working Party – which dealt with the concept of ‘freely given’, in a limited manner, predominantly in the context of personal data processing in bureaucracy and employment.³⁵ Accordingly, there is no obvious reason to think the EDPB’s position should be regarded as normatively superior to the context specific position, supported by an extensive history of ethical thought and practice, identifiable in medical research ethics.

The critiques discussed in the paragraph above could have been avoided by employing the framework outlined in the previous three sections. In the first instance, under the approach, consideration would have started from the position that EU data protection law and medical research ethics should, as far as possible, be reconciled in as cogent and just a manner as possible. This would have avoided the first logical step taken by the EDPB in considering the concept of ‘freely given’ consent in EU data protection law as separate from the same concept in medical research ethics. A subsequent consideration of the hard boundaries of EU data protection law in relation to the concept of ‘freely given’ consent – within which any discussion of reconciliation would need to take place – would have revealed a flexible concept with sparse clarification in relation to medical research ethics. A final consideration of a ‘normatively ideal’ reconciliation could have then integrated the extensive, and context-specific, considerations in medical research ethics as the primary source of design information in crafting a solution.

XI. Example Two: The case of legitimate processing

The second example concerns the oft stated, indeed apparently dominant, position in scholarship that EU data protection law does not suppose any hierarchy between the range of options it provides to legitimate the processing of personal data in medical research – in particular, the position asserts that consent does not, in any specific case, occupy a position of primacy in relation to the other ‘public interest’ justifications.³⁶

³⁴ D Peloquin, M DiMaio, B Bierer, M Barnes, ‘Disruptive and avoidable: GDPR challenges to secondary research uses of data’ (2020) 28(6) *European Journal of Human Genetics* 697, 700-701. The Board refer, in elaborating their position, to European clinical trials law, whilst making a link between the obligations on consent in European clinical trials law and medical research ethics, in particular the Declaration of Helsinki. They do so, however, only to highlight the divergence between the approach of EU data protection law and EU clinical trials law. European Data Protection Board, ‘*Opinion 3/2019*’ (n 5) 6.

³⁵ Article 29 Working Party, *Guidelines on consent under Regulation 2016/679* (Guidelines 2016, revised 2018) 6-7.

³⁶ See, for example: Chico, ‘The impact of the General Data Protection Regulation’ (n 17) 112; E Dove, J Chen, ‘Should consent for data processing be privileged in health research? A comparative legal analysis’ (2020) 10(2) *International Data Privacy Law* 117, 120 (hereafter Dove and Chen, ‘Should consent for data processing be privileged’)

This position is arrived at by taking two logical steps – both of which resemble those taken by the EDPB in arriving at their position on ‘freely given’ consent, discussed in the previous section. First, EU data protection law is conceptually detached from all other forms of law and ethics relevant to consent medical research – i.e. the law is regarded as a ‘closed’ system, the constituent parts of which are inaccessible to external, non-EU data protection law, forms of information. Second, the conclusion that the law foresees no hierarchy in relation to the justification of processing in medical research is then reached via a technical, positivistic, evaluation of the black letter law in the GDPR itself. With regard to this form of analysis, the position can be argued to be correct – it is indeed arguable that the black letter text of the GDPR does not express the primacy of consent over other ‘public interest’ justifications to legitimate processing of personal data in medical research.³⁷

As a consequence of this approach, the position can be criticized both in terms of cogency and in terms of achieving a ‘normative ideal’. In terms of cogency, the position results in a divergence in the way in which EU data protection law and medical research ethics approach the basic issue of whether, and when, the research subject should have control over their personal data are processed in medical research or not – the overwhelmingly dominant position in medical research ethics is that consent should be obtained unless this is not possible.³⁸ In terms of achieving a ‘normative ideal’, the position paints EU data protection as ambivalent concerning the ethical dimensions of the questions of whether, and when, research subjects should be able to determine for themselves their participate in research or not. These questions, however, are far from free of ethical connotations. Indeed, these questions are inseparable from considerations as to how far the research subject constitutes an entity whose will should be respected, and which is capable of exercising autonomy, in relation to medical research.³⁹

Employing the framework outlined in sections VII-IX, above, allows a solution to be reached which does not fall foul of either of the critiques highlighted in the previous paragraph. In the first instance, under the framework, consideration of the issue would have started from the position that EU data protection law and medical research ethics should, as far as possible, be reconciled in as cogent and just a manner as possible. This would have avoided the first logical step in considering EU data protection law as a completely free-standing instrument,

³⁷ There are, however, divergent opinions regarding this issue. See, for example, the conclusion of Ienca. Scheibner, Ferretti, et. al.: Marcello Ienca, James Scheibner, Agata Ferretti, et. al., *How the General Data Protection Regulation changes the rules for scientific research Study* (Report, ETH Zürich Research Collection, 2019) 60.

³⁸ See, for example, Para. 25 of the World Medical Association’s Declaration of Helsinki: ‘Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary.’

³⁹ Indeed, Dove and Chen, whilst suggesting that EU data protection law does not preference any particular justification for processing personal data in medical research, lament this position precisely for its lack of ethical reflection: ‘Enabling data subjects to provide consent demonstrates respect for them as data subjects and also establishes a communicative bond between the controller and the subject, whereby both can inform the other of their interests, rights, and duties. For these reasons, as a general principle, we think consent should be privileged to a degree in the research provisions of data protection law... Thus, we do not support the current default data protection model in Europe, reflected in the GDPR.’ Dove and Chen, ‘Should consent for data processing be privileged?’ (n 36) 129. As alternatively formulated by Taylor and Whitton: ‘a person should be compelled to suffer an interference with a common interest only in so far as necessary and consistent with public reason. People are not compelled to suffer any interference with either common interest if they provide consent to the use or disclosure of personal health data for research purposes. For this reason, where it is practicable to seek an individual’s consent to any processing of personal health data for research purposes, his or her consent to processing must normally be sought.’ MJ. Taylor, T Whitton, ‘Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data’ (2019) 9(1) *Laws* 1 16 <<https://www.mdpi.com/2075-471X/9/1/6>> accessed 3 June 2020.

separate from parallel considerations in medical research ethics. A subsequent consideration of the hard boundaries of EU data protection law in relation to the question of how personal data processing in medical research should be justified would then have revealed a flexible set of conditions with sparse clarification of hierarchy in relation to medical research ethics. A final consideration of a ‘normatively ideal’ reconciliation could have then integrated the extensive, and context-specific, considerations concerning the primacy of consent over ‘public interest’ justifications in medical research ethics as the primary source of design information in crafting a solution.⁴⁰

The previous five sections outlined a ‘normative framework’ via which cogent and just reconciliations between EU data protection law and medical research ethics might be sought. These sections, however, left a significant question open: what is to be done when the hard boundaries of EU data protection law exclude the possibility to integrate a ‘normatively ideal’ solution identifiable in medical research ethics. Whilst this is a question which, technically, falls outside the scope of the framework, it is a question worthy of some brief consideration.

XII. Options for Achieving a ‘Normative Ideal’ despite Conflict

Superficially, this looks like a question with no clear answer – a question representing an intractable problem. In certain situations, however, there may be options available to ameliorate the brisance of the problem. Three such options deserve closer discussion.

First, the medical research practice giving rise to the issue may be adapted such that both the ‘normatively ideal’ and the black letter of data protection law are respected. Data protection law is designed to be highly flexible. One aspect of this flexibility is the possibility to adopt various practical approaches to achieve compliance with substantive principles.⁴¹ In certain cases, this may open the possibility for reconfigurations of practice such that conflicts between the ethically ‘normative ideal’ and the law are simply designed out of existence. Such an approach, however, will only be available and functional in limited circumstances, defined by the following factors: i) the practice giving rise to the issue must be amenable to suitable adaptation; ii) the legal obstruction in question must be amenable to alternative approaches to compliance; iii) the adapted practice should not imply disproportionate negative impacts on research subjects, or on interests tied up with the conduct and outcome of research; and iv) the adapted practice should not imply violations of other forms of obligation – either legal or ethical.

Second, alternative pathways through the law might be sought which facilitate compliance with EU data protection law and support an ethically ‘normatively ideal’. Data protection law outlines a complex and interconnected set of conditions for personal data processing. In

⁴⁰ It should, however, be noted that the assertion that consent should, in principle, be regarded as having primacy over ‘public interest’ justifications for the processing of personal data in medical research, does not mean that there will not be instances in which this principle cannot be overridden – for example, in cases where consent cannot be obtained as an original donor of research data can no longer be found without excessive expenditure.

⁴¹ Consider, for example, the case of the conduct of Data Protection Impact Assessments (DPIAs). The GDPR explicitly requires, in Article 35(7)(c), that a DPIA include: ‘an assessment of the risks to the rights and freedoms of data subjects’. Yet, DPAs do not always necessarily require that a ‘rights and freedoms’ assessment is done. The CNIL, for example, do not appear to require such an assessment in the conduct of a DPIA. See: Privacy Impact Assessment (PIA) Methodology (Policy, 2018); CNIL, Privacy Impact Assessment (PIA) Templates (Policy, 2018); CNIL, Privacy Impact Assessment (PIA) Knowledge Bases (Policy, 2018). See, for a discussion – both of the CNIL approach and of the obligation to conduct a ‘rights and freedoms’ assessment: D. Hallinan, N. Martin, ‘Fundamental Rights, the Normative Keystone of DPIA’ (2020) 6(2) European Data Protection Law Review 178, 178-193.

certain instances, compliance is possible via multiple avenues.⁴² Such an approach, however, will only be available in limited circumstances, defined by the following factors: i) compliance is possible via different routes through the law; ii) the alternative route through the law does not cause disproportionate cogency issues; and iii) the alternative route through the law does not cause disproportionate negative impacts on research subjects, or on interests tied up with the conduct and outcome of research. The UK NHS provides an example of this approach. In order to legitimate research on the basis of consent, whilst working under the assumption that the GDPR's consent conditions prohibit consent for research with NHS data, the NHS propose the following: legitimisation for research processing under the GDPR should follow a 'public interest' justification whilst consent should still be obtained as a supplemental ethical necessity.⁴³

Third, legal change might be sought which would secure the enshrinement of the 'normatively ideal' reconciliation in the *aequis* of EU data protection law relevant to medical research. In this regard, the ability of the medical research community to influence the path of EU data protection law has already been demonstrated.⁴⁴ In turn, any effort to secure legal change would – accepting, *prima facie*, the legitimacy of the position lobbied for – rest on normatively defensible grounds. There are several objections which might be raised as to the utility of this approach. One objection is that, during the period in which legal change is sought, a sub-optimal normative position would be the default within the 'common normative system of rules'. Another objection is that – even despite an effort to obtain change – there is no guarantee that the desired outcome will be secured.

There is a final, fundamental, objection which might be raised against the possibility to secure legal change in EU data protection law: that the relevant legislative processes which led to the adoption of EU data protection law are now closed and will not be reopened – likely for many years – and, accordingly, there are now no relevant pathways to secure legal change. Superficially, this final objection seems a particularly. A closer look, however, reveals its flaws.

XIII. The Ongoing Potential for Legal Change in EU Data Protection Law

Unlike more traditional command-and-control law, EU data protection law under the GDPR includes several interpretation and adaptability mechanisms aimed at allowing the substantive principles of the law to mold to novel technological and social contexts.

The most important of these mechanisms are the broad interpretation and adaptation powers granted to Data Protection Authorities (DPAs) – at national level – and the EDPB – at European level. These powers are inscribed into the GDPR itself. For example, in Article 58(3)(b), national DPAs are endowed with the power to 'issue...opinions...on any issue related to the protection of personal data' whilst in Article 70(1)(e) the EDPB is given the power to 'examine, on its own initiative, on request of one of its members or on request of the

⁴² This is particularly the case in relation to the legitimisation of processing under Articles 6 and 9 of the GDPR.

⁴³ By highlighting the approach of the NHS, I do not suggest that the interpretation of the GDPR offered by the NHS is necessarily correct. The approach taken by the NHS simply provides an example of this form of approach. See: NHS Health Research Authority, 'Consent in research' (NHS Health Research Authority, last updated 19 April 2018) <<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/>> accessed 30 November 2020.

⁴⁴ See, for example: Beth Thompson, 'Data protection: how medical researchers persuaded the European Parliament to compromise' (LSE Blog, 11 February 2016) <<https://blogs.lse.ac.uk/brexit/2016/02/11/data-protection-how-medical-researchers-persuaded-the-european-parliament-to-compromise/>> accessed 26 November 2020,

Commission, any question covering the application of this Regulation’. National DPAs and the EDPB have already shown their willingness to use these powers and their guidance is treated as carrying substantial weight in the interpretation of EU data protection law – following only legal texts and court decisions in significance.⁴⁵

These powers are capable of being used to introduce broad change into EU data protection law. Naturally, given their focus on interpretation and adaptation, these powers have limits. DPAs and the EDPB cannot introduce changes which clearly contradict the legal texts or jurisprudence. Nor can they introduce changes to the law which explicitly move against its base rationale. However, the powers can be used to provide extensive interpretations of the broad range of vague provisions and principles in the law as well as to reinterpret existing DPA and EDPB guidance on the law. The scope of these powers has also, hitherto, been interpreted broadly by DPAs and the EDPB. Indeed, the powers have even been used to introduce novel forms of substantive principle into EU data protection law – for example, in the form of the Binding Corporate Rule international transfer mechanism.⁴⁶

Accordingly, these interpretation and adaptation mechanisms provides a viable avenue of legal change through which ‘normatively ideal’ reconciliations could be integrated into the *aequis* of EU data protection law applicable to medical research on an ongoing basis. It is certainly the case that DPAs and the EDPB feel themselves suitable bodies to provide guidance in relation to medical research.⁴⁷ Use of such these mechanisms in this capacity, however, will only be possible in certain circumstances, defined by the following features: i) the legal obstruction in question cannot be an unavoidable product of legal text or jurisprudence – i.e. the legal obstruction would need to emerge from prior guidance or be amenable to plausible alternative interpretation; ii) the relevant DPA(s) or the EDPB would need to be ready to accept and to adopt the relevant ‘normatively ideal’ reconciliation defined in medical research ethics.⁴⁸

In this regard, there are indeed possibilities for ongoing legal change in EU data protection law which could facilitate the integration of ‘normatively ideal’ reconciliations. These possibilities are, however, necessarily limited in scope.

XIV. Conclusion

⁴⁵ As De Hert and Papakonstantinou observe in relation to the EDPB, for example: ‘[the GDPR foresees a] strong and standalone Board...that is capable of deciding on...and enforcing...opinions’. P De Hert, V Papkonstantinou, ‘The new General Data Protection Regulation: Still a sound system for the protection of individuals?’ (2016) 32(2) Computer Law and Security Review 179, 193.

⁴⁶ The mechanism was introduced by the Article 29 Working Party, the forerunner to the EDPB. See: L Moerel, *Binding Corporate Rules: Corporate Self-Regulation of Global Data Transfers* (Oxford University Press: Oxford, 2012) 23.

⁴⁷ Consider, for example, the choice of the German Datenschutzkonferenz to offer their opinion on the legitimacy of broad consent in medical research under the GDPR: Datenschutzkonferenz, *Beschluss der 97. Konferenz der unabhängigen Datenschutzaufsichtsbehörden des Bundes und der Länder zu Auslegung des Begriffs „bestimmte Bereiche wissenschaftlicher Forschung“ im Erwägungsgrund 33 der DS-GVO* (Guidance, 2019). Consider equally the position of the EDPB in relation to consent in medical research under the GDPR: European Data Protection Board, *Guidelines 05/2020 on consent under Regulation 2016/679* (Guidelines, Version 1.1, 2020) 30-32.

⁴⁸ This may not always be the case. For example, one might consider a ‘normatively ideal’ reconciliation in relation to the concept of freely given consent in clinical trials to build on the considerable ethical thought on the matter in medical research ethics on clinical trials. This is not, however, an approach apparently favoured by the EDPB in their approach to the interpretation of ‘freely given’ consent under the GDPR in relation to clinical trials: European Data Protection Board, *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)* (Opinion 2019) 6.

In the last few years there has been considerable confusion as to how EU data protection law and medical research ethics should relate to one another. This confusion has flourished, at least in part as a result of the fact there have been few holistic, structured, efforts to bring clarity to the issue.

In this regard, this article sought to provide a ‘normative framework’ for the reconciliation of EU data protection law and medical research ethics. The framework is designed to be generally relevant for all contexts and levels at which EU data protection law and medical research ethics come into contact and should thus be useful for academics, policy-makers and practitioners alike.

In the first instance, the article highlighted the fact that data protection law and medical research ethics both constitute rule-sets which form part of a ‘common normative system of rules’ for the channelling of behaviour in medical research. In this regard, when the rule-sets overlap in relation to a given issue, they should ideally be reconciled in a way which is both cogent and just.

The article then proceeded to elaborate a ‘normative framework’ to achieve, in relation to any given issue, a cogent and just reconciliation between EU data protection law and medical research ethics. The first part of this framework consists in the identification of the hard boundaries set by EU data protection law in relation to the issue at hand. As statutory law, data protection holds unique social value, and its hard conditions must thus be regarded as having primacy over any competing conditions outlined in medical research ethics.

The second part of the framework then consists of the identification of a ‘normatively ideal’ reconciliation – within the hard boundary criteria set by data protection law. In this regard, the primary source of relevant normative information for the construction of such a reconciliation should be medical research ethics. Medical research ethics is, after all, the rule-set which will usually contain the greatest concentrated normative thought on any given issue in medical research ethics.

There are, however, exceptions to this general principle where thought in data protection law may fill gaps, or augment, positions thought present in medical research ethics. This will be the case, for example, when an issue involves constellations of data processing actors, forms of data processing, or social or legal norms which have hitherto received more attention in EU data protection law than in medical research ethics.

Whilst the identification of a cogent and just reconciliation may be ideal, this may of course not always be possible – for example if the hard boundaries of EU data protection law exclude the possibility to incorporate a ‘normatively ideal’ position already outlined in medical research ethics. In this case, the article proposed three possible approaches to move forward.

First, it may be possible, in certain cases, for a research practice to be adapted such that both a ‘normatively ideal’ and the black letter of EU data protection law are respected. Second, it may be possible, in certain cases, to identify an alternative pathway through EU data protection law which facilitates enactment of a ‘normatively ideal’. Finally, the article highlighted the possibility to agitate for legal change.

There may be doubt as to the utility of the final approach. Doubts emerge, in particular, given the fact that there is no current legislative process aimed at EU data protection law reform. It should be recalled, however, that EU data protection law incorporates several mechanisms for

ongoing legal adaptation and interpretation. These may be suitable, in certain circumstances, to integrate ‘normatively ideal’ positions into the *aequis* of the law.